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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/722,000

11/25/2003

Peter L. Collins

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

01/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/722,000 | COLLINS ET AL. | |
| | Examiner | Art Unit | |
| | Zachariah Lucas | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,14-20,22-33,35-48,52 and 55-65 is/are pending in the application.
- 4a) Of the above claim(s) 5-11,15-17,25-27,29-33,37-45,52 and 55-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,4,14,18-20,22-24,28,35,36 and 46-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/23/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 4-11, 14-20, 22-33, 35-48, 52, and 55-65 are pending in the application.
2. In the prior action, mailed on September 24, 2007, claims 1-11, 14-20, and 22-65 were pending in the application; with claims 3, 5-11, 15-17, 25-27, 29-33, 37-45, and 49-55 withdrawn from consideration; and claims 1, 2, 4, 14, 18-20, 22-24, 28, 34-36, and 46-48 under consideration and rejected.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 24, 2008 has been entered.

In the amendment of October 24, 2008, the Applicant cancelled claims 2, 3, 34, 49-51, 53, and 54; and amended claims 1, 52, and 64.

4. Claims 1, 4, 14, 18-20, 22-24, 28, 35, 36, and 46-48 are under consideration.

Election/Restrictions

5. Applicant's comments regarding the restriction requirement are noted. As the restriction has already been made Final, and as the claims are not presently in condition for allowance, the restriction is maintained until such time as allowable products have been identified. Applicant's assertion that the claims represent a unitary invention and would impose no undue burden of examination is not found persuasive for the reasons of record, and because each of the various

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claimed inventions would require separate, non-coextensive, searches. As the restriction has been made Final, any additional argument with respect to the restriction requirement should be made by Petition under 37 CFR 1.144.

Any issue of rejoinder of non-elected methods will be addressed upon indication of an allowable product.

Priority

6. **(New Objection)** Applicant is requested to amend the statement of priority submitted on July 18, 2007 by indicating the present status of the non-provisional U.S. applications (i.e. indicate that they have been issued as patents, and provide the U.S. Patent number).

7. **(New Objection)** It is noted that the present application does not provide a proper reference to the parent applications. For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications, and reference to a non-provisional application as claiming benefit of such provisional applications (i.e. another application is not a continuation, divisional, or continuation-in-part of a prior provisional application). See e.g., MPEP 201.11 III A. and B. MPEP 201.11 III.B specifically indicates that provisional applications should not specify a relationship (other than as a non-provisional of, or claiming priority to or benefit of such provisional applications).

8. **(New Objection)** Moreover, while the Applicant inserted the statement of priority in the amendment of July 18, 2007, the Applicant did not delete the prior, incorrect, statement of

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priority presented on the first page of the application as filed. Applicant is requested to delete this earlier version of the priority statement.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **(Prior Rejection- Withdrawn)** Claims 1, 4, 14, 18, 19, 22-24, 35, 36, and 46-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (U.S. 5,840,520) and Collins (PNAS 92: 11563-67), and further in view of Murphy et al. (U.S. 5,922,326). Claim 1 has been amended to incorporate the limitations of claim 2. The rejection is therefore withdrawn.

11. **(Prior Rejection- Maintained)** Claims 1, 2, 4, 14, 18, 19, 22-24, 34-36, and 46-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (U.S. 5,840,520) and Collins (PNAS 92: 11563-67), and Murphy et al. (U.S. 5,922,326), and further in view of Wertz et al. (U.S. 5,789,229). The rejection is maintained over pending claims 1, 4, 14, 18, 19, 22-24, 28, 35, 36, and 46-48.

The Applicant traverses the rejection on the basis that the cited references do not teach the specific nucleotide sequences of the mutant viruses, and that knowledge of these changes is critical to the claimed invention.

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The argument is not found persuasive. While those in the art may not have known where in the (e.g.) RSV cpts 248 viral genome the attenuating mutations are located, the art does indicate that those of ordinary skill in the art would be able to identify genomes that retain the attenuating mutation through the performance of routine assays, Such as the plaque assays described by the Murphy reference (columns 10-11). Even if Applicant's argument is accepted that those of ordinary skill in the art could not make the substitutions suggested by the art with certainty, the combination of such substitution mutants with the attenuated genomes of Murphy would have been obvious to try. See, KSR International Co. v. Teleflex Inc., 82 U.S.P.Q.2d 1385, at 1397 (USSC 2007- indicating that an invention may be found obvious to try where the art identifies a finite number of potential predictable solutions, a person of ordinary skill in the art has reason to pursue the known solutions, and it is within the ability of those of ordinary skill in the art to pursue such potential solutions). Those of ordinary skill in the art would have had the motivation to combine the teachings of cited references to make the substitutions in the attenuated genomes of Murphy for the reasons described in the prior actions. The teachings of this reference also indicate that it would have been within the skill of those of ordinary skill in the art to make and test such mutants for desired levels of attenuation using the methods referred to above. Thus, the rejection is maintained as a rejection of the claims as obvious to try for the reasons above, and the reasons of record.

12. **(New Rejection)** Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke, Collins, Murphy, and Wertz as applied above, and further in view of the teachings of Connors et al. (Virology 208:478-84- reference CH in the July 2008 IDS) and Randolph et al.

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(US 5,932,222). This claim is directed to embodiments of the claimed RSV wherein the chimeric genome or antigenome comprises at least one attenuating mutation stabilized by multiple nucleotide changes in the codon specifying the mutation. This limitation is not taught or suggested by the teachings of the previously cited references.

However, Randolph teaches that a mutation may be stabilized through the use of multiple genetic lesions (changes). Connors teaches four potentially attenuating mutations to an RSV genome. From the teachings of Connors, it would have been obvious to those of ordinary skill in the art to make an attenuated RSV comprising one of the attenuating mutations disclosed therein. While the reference is not clear as to which of the mutations actually causes an attenuated phenotype, because the reference discloses the four mutations, at least one of which causes the attenuation, the reference renders obvious to try recombinant RSV viruses comprising the attenuating mutation. The additional teachings of Randolph render obvious the use of multiple nucleotide changes in the relevant codon to stabilize the attenuating mutation once identified.

In view of these teachings, it would have been obvious to those of ordinary skill in the art to incorporate the mutation into the chimeric RSV suggested by the previously described references as a means for the further attenuation and optimization of the chimeric RSV virus. The combined teachings of these references therefore render the claimed invention obvious.

Double Patenting

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13. **(Prior Warning- Withdrawn)** Applicant was advised that should claim 3 be found allowable, claim 34 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. In view of the cancellation of the claims, the warning is moot.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. **(Prior Rejection- Maintained)** Claims 1, 4, 14, 18, 19, 20, 22-24, 28, 35, and 46-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 12, 14, 18, 20-25, 28, and 31-34 of U.S. Patent No. 6,689,367. With respect to this rejection, the Applicant again asserts that the present rejection should not be made in view of the presence of a restriction requirement in the application from which that patent was issued is noted. The argument was previously not found persuasive in view of (a) the fact that the patented claims specifically read on species of the presently claimed inventions and the present claims read on the patented claims (i.e. claims presented in these applications are not consonant with the restriction requirement- see e.g., MPEP 804.01); and (b) that the restriction requirement in that

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application was withdrawn in the Notice of Allowance mailed in that application on August 26, 2003. Applicant's attention is directed to MPEP section 804.01, and specifically to situations (B) and (E) in that section in which the prohibition against double patenting under 35 U.S.C. 121 does not apply. The rejection is therefore maintained.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648